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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/091,222	03/01/2002	Gary S. Grubb	AHPWA16BUSA	3024
270	7590	10/02/2003	EXAMINER	
HOWSON AND HOWSON ONE SPRING HOUSE CORPORATION CENTER BOX 457 321 NORRISTOWN ROAD SPRING HOUSE, PA 19477			HUI, SAN MING R	
			ART UNIT	PAPER NUMBER
			1617	
DATE MAILED: 10/02/2003				

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/091,222

Applicant(s)

GRUBB ET AL.

Examiner

San-ming Hui

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-34 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All   b) ☐ Some \*   c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: .

**DETAILED ACTION**

***Election/Restrictions***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-24, 33, and 34, drawn to a method of contraception comprising administration of a progestational agent, ethinyl estradiol, and an antiprogestin agent in three phases where the first phase involves administration of a progestational agent and ethinyl estradiol, and the second phase involves administration of an antiprogestin agent, classified in class 514, subclass 171, 392, 224.2, 230.5, 255.06.
- II. Claims 25-26, drawn to a method of contraception comprising administration of a progestational agent, ethinyl estradiol, and an antiprogestin agent in three phases where the first phase involves administration of a progestational agent and ethinyl estradiol, and the second phase involves administration of an antiprogestin agent and ethinyl estradiol, classified in class 514, subclass 171, 392, 224.2, 230.5, 255.06.
- III. Claims 27-28, drawn to a pharmaceutical kit for oral administration comprising a progestational agent and an antiprogestin agent, classified in class 514, subclass 171, 392, 224.2, 230.5, 255.06.
- IV. Claims 29-32, drawn to a pharmaceutical kit for oral administration comprising a progestational agent, ethinyl estradiol, and an antiprogestin agent, classified in class 514, subclass 171, 392, 224.2, 230.5, 255.06.

The inventions are distinct, each from the other because of the following reasons:

Inventions I, and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation. The invention of Group I differs from Group II in that the second phase of Group I involves administration of an antiprogestin agent, whereas the second phase of Group II involves administration of an antiprogestin agent and ethinyl estradiol. Thus, the invention of Groups I and II operate by the administration of different agents at different times.

Inventions III and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have a different mode of operation. The invention of Group III employs two agents: a progestational agent and an antiprogestin agent. The invention of Group IV employs three agents: a progestational agent and an antiprogestin agent and ethinyl estradiol. Thus, the invention of Groups III and IV operate by the administration of a distinct set of active agents.

Inventions III-IV and I-II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the

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pharmaceutical kit product can be used in a materially different process of using that product such as in the treatment of dysmenorrhea.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

### ***Election of Species***

Claims 1-5 and 28-39 are generic to a plurality of disclosed patentably distinct species comprising antiprogesterin agents which are represented by compound of Formula 1 (See, e.g., claim 1).

Some of these include, for example,

5-Bromo-2-oxo-2,3-dihydro-benzimidazole-1-carboxylic acid, classified in class 514, subclass 392;

6-(3-Nitro-phenyl)-3H-benzoxazol-2-one, classified in class 514, 230.5;

2-ethyl-7-(3-nitro-phenyl)-4H-benzo[1,4]thiazin-3-one, classified in class 514, subclass 224.2;

5-(3,4-dihydro-4-methy-2-oxo-quinaxalin-6-yl) thiophene-3-carbonitrile, classified in class 514, class 255.06.

Due to the structural dissimilarities of active antiprogesterin compounds encompassed by the claims and their corresponding diversity in classification, the search for all species presents an undue burden on the office.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species of antiprogesterin compound, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Because the above restriction/election requirement is complex, a telephone call to applicant's agent to request an oral election was not made. See M.P.E.P. Sec. 812.01.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to San-ming Hui whose telephone number is (703) 305-1002. The examiner can normally be reached on Mon 9:00 to 1:00, Tu - Fri from 9:00 to 6:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, PhD., can be reached on (703) 305-1877. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

San-ming Hui  
Patent Examiner  
Art Unit 1617



**SREENI PADMANABHAN**  
**SUPERVISORY PATENT EXAMINER**

10/1/03